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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,100	06/29/2007	Meiyu Geng	09548.1045USWO	7023
52835	7590	08/18/2010	EXAMINER	
HAMRE, SCHUMANN, MUELLER & LARSON, P.C.			MAIER, LEIGH C	
P.O. BOX 2902				
MINNEAPOLIS, MN 55402-0902				
			ART UNIT	PAPER NUMBER
			1623	
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			08/18/2010	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/594,100	<b>Applicant(s)</b> GENG ET AL.	
	<b>Examiner</b> Leigh C. Maier	<b>Art Unit</b> 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2010 and 12 July 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 11-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 11-17, 19 and 20 is/are allowed.
- 6) ☒ Claim(s) 18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of the Claims***

Claims 11, 12, 14, 15 and 18-20 have been amended. Claims 11-20 are pending.

Any objection or rejection not expressly repeated has been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The declaration under 37 CFR 1.132 filed July 16, 2010 is sufficient to partially overcome the rejection of claim 18 based upon 35 USC 112, 1<sup>st</sup> paragraph (with respect to treatment using the full scope of the recited oligosaccharides). The partial translation of CN 03138976.7 overcomes the rejection of claims 11-13, 19 and 20 based upon 35 USC 102(a).

### ***Claim Rejections - 35 USC § 112***

Claims 18 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling the use of the recited oligosaccharides in (1) the treatment of type 2 diabetes; (2) the treatment of type 1 diabetes in combination with insulin (but this particular method does not appear to be supported); or (3) the treatment of Alzheimer's disease (AD), does not reasonably provide enablement for the prevention of either type of diabetes or the prevention of AD or treatment for the full scope of oligosaccharides. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claims are not particularly broad in scope and one of ordinary skill in the art would be expected to be a highly trained practitioner. However, the prevention of the recited diseases remains problematic and unpredictable.

The instant disclosure demonstrates that the 6-mer has blood glucose lowering capacity in mice having induced diabetes, similar to the effect of dimethyldiguanide (metformin). Davies et al (Diabetic Medicine, 2004) discusses the difficulties involved in the prevention of diabetes, including the use of pharmaceutical agents. See, particularly the text at pp 405-408 and Table 2. This reference reports spotty positive results using such agents. However, in general, the results are negative. Therefore, there is nothing to suggest that one of ordinary skill would have a reasonable expectation that an agent known to treat type 2 diabetes would also prevent it.

The prevention of type 1 diabetes is even more difficult particularly because it is more difficult to screen and select patients who are at increased risk. See discussion in Skyler et al (Diabetes Care, 2005). This reference finds that the administration of insulin, the standard treatment of type 1 diabetes, does not delay the onset of the disease in relatives of known patients having the disease. There is no evidence that the use of the instant product would have any benefit in the prevention of type 1 diabetes. Further regarding treatment, as noted, insulin is the standard treatment for type 1 diabetes. While a combination of the instant product with insulin, as with metformin and insulin as described by Hamilton et al (Diabetes Care, 2003), might be beneficial to the treatment of type 1 diabetes, there is no evidence that this product would be beneficial to patients in the absence of exogenous insulin.

The prevention of AD is more challenging still. Doraiswamy et al (Exp. Opin. Pharmacother., 2006) discusses the difficulties at length. See particularly sections 2, 3 and 4.10.

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Although AD is an intensely studied disease, the actual cause remains a mystery, and any potential surrogate biological markers for prevention have not been validated. Prevention trials are expensive and take many years. See section 5.

In view of the foregoing difficulties associated with prevention of the recited diseases, one of ordinary skill would require undue experimentation to implement this method commensurate with its scope.

Applicant's arguments filed May 28, 2010 have been fully considered but they are not persuasive.

With respect to AD, Applicant cites data to indicate that the full scope of the oligosaccharides have binding affinity for A $\beta$  and therefore are therapeutic candidates for AD. The examiner agrees. However, there does not appear to be an argument addressing the enablement of prevention.

With respect to prevention, Applicant states "type 2 diabetes also is related to the deposition of A $\beta$ , the subsequent fibrillogenesis and increased free oxidative radicals, which give rise to the fact that inhibition of the fibril formation of A $\beta$  becomes the perspective for the for the prophylaxis and treatment of diabetes." With respect to AD, it appears that Applicant's argument is that in treating diabetes, one would inherently prevent AD.

First of all, while AD appears to be correlated with type 2 diabetes, the relationship remains controversial. See Biessels et al (Lancet Neurol., 2006). This reference concludes "The risk factors and mechanisms that drive the association between diabetes and accelerated cognitive decline and dementia need to be identified before adequate treatment measures [that is,

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prevention of dementia] can be developed.” (Conclusion, page 71) The state of the art remains much too unpredictable to expect AD prevention to be inherent in the treatment of diabetes.

In any case, this argument does nothing to address the non-diabetic population. Applicant demonstrates some results related to AD treatment, there are none with respect prevention. Neither has Applicant addressed the known difficulties with prevention discussed above.

With respect to prevention of diabetes, it is not clear how inhibition of the fibril formation of A $\beta$  is related to the prevention of this disease.

***Allowable Subject Matter***

Claims 11-17, 19 and 20 are allowed. Upon further consideration, the stated intended use in claim 19 has no bearing on the lack of enablement for prevention discussed above. A claim drawn to the treatment of type 2 diabetes or AD comprising the administration of an effective amount of the recited oligosaccharides would also be allowable.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Examiner's hours, phone & fax numbers***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Thursday and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Anna Jiang at (571) 272-0627, may be contacted. The fax number for Group 1600, Art Unit 1623 is (703) 872-9306.

Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished application is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

/Leigh C. Maier/  
Primary Examiner  
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